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IN THE UNITED STATES COURT FOR THE DISTRICT OF UTAH  
NORTHERN DIVISION

BY: DEPUTY CLERK

TRANSONIC SYSTEMS, INC., a New York  
Corporation,

Plaintiff,

vs.

NON-INVASIVE MEDICAL  
TECHNOLOGIES CORPORATION, d/b/a  
IN-LINE DIAGNOSTICS CORPORATION,

Defendant.

ORDER GRANTING NMT'S  
MOTION FOR SUMMARY  
JUDGMENT ON THE ISSUE OF  
INFRINGEMENT

Case No. 1:99-CV-00041 PGC

This patent dispute is before the court on a host of motions for summary judgment. Plaintiff Transonic Systems Inc. (Transonic) claims that defendant Non-Invasive Medical Technologies (NMT) infringed on U.S. Patent No. 5,685,989 ("the '989 patent") in three inventions that measure the rate of blood flow through a dialysis shunt. These three inventions are known as  $\Delta H$ , Saline Dilution, and Go-No Go. The court held a hearing on this matter on May 4, 2004, at which all sides were capably represented. The court finds for NMT, concluding that (1)  $\Delta H$  does not "calculate" the rate of blood flow as defined by the patent, (2) the Saline Dilution method was never used after the '989 patent issued, and (3) the Go-No Go method does not use any of the equations specified in the '989 patent. Accordingly, the court grants NMT's motion for summary judgment on the issue of infringement. All other pending summary

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judgment motions are denied as moot.

## **I. THE TECHNOLOGY**

To understand the technology at issue here, it is necessary to know a little about kidney dialysis. The critical feature of dialysis for present purposes is that a tube, or shunt, is surgically implanted in the body, creating a sort of artificial blood vessel. This shunt becomes an access point for inserting tubes that will direct blood flow out of the body and through a dialysis machine. The dialysis machine acts as an artificial kidney, cleaning the blood, which then returns through a tube into the shunt and back into the normal blood stream.

This process of dialysis can be seriously complicated if the shunt becomes dirty and clogged. If clogging is left unattended, the shunt will eventually need to be surgically replaced. This result can be avoided by monitoring blood through the shunt. By monitoring blood flow, clogging can be discovered early on, and it is possible to repair or clean the shunt rather than having to replace it.

To this end, the inventions involved in this case were created. Both Transonic and NMT's technologies do essentially the same thing—they mix some substance with blood flowing through the shunt, which changes certain characteristics in the blood. Based on those changes, the inventions calculate, as the word is commonly used, the rate of blood flow through the shunt.

## **II. PROCEDURAL HISTORY**

The significance of the '989 patent has been the subject of ongoing litigation in this court and the Federal Circuit since 1999. The critical independent claims are 1 and 9, which have been

stated in there entirety elsewhere in this case.<sup>1</sup> These claims included a number of limitations whose significance was disputed. These limitations include the terms “mixing,” “changing a selected blood parameter,” “calculating,” and “determining.” While the meaning of most of these terms is now well settled, the significance of “calculating” and “determining,” which the parties agree is the same for both limitations, has taken this case to the Federal Circuit twice and is the focus of the pending motions. Accordingly, the court will only address the prior case law as it treats these terms.

Transonic’s ‘989 patent claims to “calculate” and “determine” the rate of blood flow through the shunt. After a *Markman* hearing, this court construed these terms as they are commonly used: “to determine by mathematical equation.”<sup>2</sup> Based on the construction of these and other terms, on November 8, 2000, the court concluded that because both technologies calculated blood flow, as the term was commonly used, NMT’s product was infringing and entered a preliminary injunction, enjoining it from selling its automated  $\Delta H$  monitor.<sup>3</sup>

In the first appeal in this case, the Federal Circuit disagreed (*Transonic I*).<sup>4</sup> In deciding what “calculating” meant, the Circuit looked beyond the patent claims to the specification and the prosecution history. The Circuit quoted several places where Transonic arguably limited its method of calculating to eight equations set forth in the patent. In light of this language, the

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<sup>1</sup>See *Transonic Sys. Inc. v. Non-Invasive Medical Techs. Corp.*, 75 Fed. Appx. 765, 770–71, 773 n.1 (Fed. Cir. 2003) (hereinafter *Transonic II*); *Transonic Sys. Inc. v. Non-Invasive Medical Techs. Corp.*, 10 Fed. Appx. 928, 930 (Fed. Cir. 2001) (hereinafter *Transonic I*).

<sup>2</sup>Op. & Order of Dec. 13, 1999 (#48-1) at 7–9.

<sup>3</sup>Mem. Op. & Order of Nov. 8, 2000 (#193-1) at 5–7.

<sup>4</sup>*Transonic I*, 10 Fed. Appx. 928.

Circuit stated that “Transonic disclaimed any interpretations of the terms ‘calculating’ and ‘determining’ that do not reflect the stated significance of the disclosed equations to the invention as a whole.”<sup>5</sup> The Circuit then held that “the claim terms ‘calculating’ and ‘determining’ must be construed as requiring the use of at least one of the equations set forth in the specification of the ‘989 patent.”<sup>6</sup>

*Transonic I* sent the case back to this court, and discovery moved it to the summary judgment stage. Based on the language quoted above, this court concluded, as a matter of law, that NMT’s product could not have infringed the ‘989 patent because it was “undisputed that NMT’s accused methods do not specifically use the exact equations defined in the specification of the ‘989 patent.”<sup>7</sup> The court granted summary judgment for NMT on the infringement issue, and the case was appealed once again to the Federal Circuit.

On the second appeal to the Federal Circuit (*Transonic II*),<sup>8</sup> the circuit recognized the reasonableness of this court’s order but nonetheless reversed, concluding that “the term ‘calculating’ is [not] limited to the exact equations disclosed in the ‘989 patent specification.”<sup>9</sup> Although *Transonic II* reaffirmed the earlier proposition that “Transonic disclaimed any interpretations of the terms ‘calculating’ and ‘determining’ that do not reflect the stated significance of the disclosed equations to the invention as a whole,” it recognized that the

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<sup>5</sup>*Id.* at 934.

<sup>6</sup>*Id.*

<sup>7</sup>Mem. Op. & Order of Sept. 14, 2001 (#440-1) at 4.

<sup>8</sup>*Transonic II*, 75 Fed. Appx. 765.

<sup>9</sup>*Id.* at 776.

specification also contemplated that several different indicators could be mixed with the blood, each producing different quantifiable effects on the blood characteristics.<sup>10</sup> Accordingly, the equations would have to be modified to account for the different indicator, which would mean the patent covered equations other than the literal equations stated in it.

The court stated the test for whether some equation other than the eight specified was covered by this claim:

Equations that *embody the mathematical relationships disclosed by the specification*, but are modified for a specific indicator, are within the scope of the claims. . . . Accordingly, we conclude that the terms “calculating” and “determining” *must use at least one of the equations set forth in the specification of the ‘989 patent*, i.e., “ $Q=V/S$ ”, but that the claims also cover the use of indicators other than saline. In other words, *the elements of the equation, “V” and “S”, may be altered to account for the characteristics of different indicators, such as saline, temperature, etc., so long as the relationships set forth in the equations in the specification are still expressed.*<sup>11</sup>

The Circuit remanded the case to this court for further consideration, and the case was transferred to the undersigned judge. From the Circuit’s holding, three guiding propositions emerge that govern the resolution of the pending summary judgment motions. First, and consistent with *Transonic I*, the disputed equation still must be “one of the equations set forth in the specification of the ‘989 patent.” Second, now moving beyond the holding of *Transonic I*, an equation that is not listed among the eight is still “one of” those equations *only if* it “embod[ies] the mathematical relationships disclosed by the specification.” Finally, an equation that is not listed in the specification is “one of” those equations *only if* it is merely an alteration of “the elements of [a listed] equation.”

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<sup>10</sup>*Id.* at 775–76.

<sup>11</sup>*Id.* at 776–77 (emphasis added).

The last line of the passage quoted above makes clear *Transonic II* did not create two separate tests, as Transonic argues, but a single test: does an unspecified claim embody the same mathematical relationships disclosed by the specification? To be sure, this difficult concept has both a qualitative and a quantitative component. The qualitative aspect is that the disputed equation must “embody the same mathematical relationship” as a specified equation; this is demonstrated quantitatively by an equation whose elements are mere alterations of the elements of a specified equation.

### III. THE MATHEMATICAL RELATIONSHIP

Though simple to state, this test requires the court to determine conceptually what mathematical relationship the Federal Circuit envisioned at the core of the specified equations. NMT argues that this core is the relationship between time and the change caused by indicator as shown on a dilution *curve*. Transonic argues that the core mathematical relationship is any indicator dilution *equation*. The court agrees with Transonic.

At the outset, the court notes that the Federal Circuit nowhere mentions the relevance of indicator dilution equations to the “calculating” limitation. The only mention of such equations is in a passing reference to Transonic’s argument that the claim covers any indicator dilution equation. The fact that the circuit did not return to this topic suggests that such equations do not characterize the core relationship.

On the other hand, the Federal Circuit repeatedly emphasized the significance of dilution curves in the equations. It cites the specification to point out that the purpose of the indicators was “to create a dilution curve.”<sup>12</sup> The specification, in explaining that different indicators could

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<sup>12</sup>*Id.* at 776 (citing ‘989 patent, col. 1, ll. 66–67 & col. 2, ll. 1–17).

be used, specifically notes that the various indicators would be used “to produce dilution curves.”<sup>13</sup> The Circuit also highlighted the fact that the very detail that distinguished the ‘989 patent from prior art was the fact that “shunt flow is calculated from a dialysis flow and a concentration curve measurement.”<sup>14</sup> In light of these many references to the dilution curve, and in the absence of any reference to indicator dilution equations, the court concludes that the relationship contemplated by *Transonic II* is the relationship expressed in the calculation of a dilution curve.

Having concluded that the relationship embodied by the specified equations involves the calculation of a dilution curve, the court now looks at each of NMT’s allegedly infringing technologies.

#### IV. $\Delta H$

##### A. *Dilution Curve*

Because indicator dilution equations are not the relationship contemplated by the Federal Circuit, the court need not consider whether  $\Delta H$  equations are indicator dilution equations. The only relevant consideration is whether  $\Delta H$  requires calculation of a dilution curve. The court concludes it does not. Unlike the Transonic method, which integrates the area under two separate curves,  $\Delta H$  plots three separate points, which are never calculated in a concentration curve. Moreover, there is evidence that Transonic’s expert Daniel Maynes admitted that  $\Delta H$  did

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<sup>13</sup>*Id.* (quoting ‘989 patent, col. 1, ll. 66–67 & col. 2, ll. 1–17).

<sup>14</sup>*Id.*

not require calculation of the area under the curve.<sup>15</sup> Although NMT pleadings include a number of graphical representations that show various graphs and curves, Transonic has not offered evidence to show that these graphical representations reflect key components of the  $\Delta H$  equations or demonstrated how these graphs would be used. Moreover, the court is not persuaded by Transonic's argument that the graphical representation of a steady stream injection represents a series of many dilution curves. Based on the undisputed facts, Transonic has not proven the  $\Delta H$  equations are such a series.

In addition to this evidence that  $\Delta H$  does not involve a dilution curve, the court notes that Transonic and  $\Delta H$  equations differ in the variables they account for. For example,  $\Delta H$  does not calculate or use a dialysis flow rate, a factor that was necessary to distinguish Transonic's technology from prior art.<sup>16</sup> Furthermore, there is evidence that Transonic's technology must be implemented before the blood has the chance to travel through the circulatory system. Although Transonic argues that its equations can account for travel through the circulatory system, this detail is another piece of evidence supporting the court's conclusion that the different technologies are measuring and evaluating different things.

For these reasons, the court concludes that the  $\Delta H$  equations do not embody the same relationship as the equations claimed in the '989 patent.

*B. Altered Elements*

To resolve the pending motions, it is probably enough to conclude that  $\Delta H$  does not

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<sup>15</sup>Decl. of Ricardo Rodriguez in Supp. of Def. NMT's Reply to Mot. for Partial Summ. J. of Non-Infringement, Ex. 4, Depo. of Daniel Maynes at 131.

<sup>16</sup>See 75 Fed. Appx. at 775.



involve a dilution curve. Nevertheless, Transonic's other argument that the  $\Delta H$  equations are mere alterations of Transonic's eight specified equations is worth discussing briefly.

Transonic offers two reasons why it believes the  $\Delta H$  equations satisfy the quantitative test set forth in *Transonic II*. First, it claims that on March 19, 1997, Dr. John Leypoldt, one of the NMT inventors, wrote a letter to '989 inventor Dr. Nikolai Krivitski, explaining that the  $\Delta H$  was derivable from one of the '989 indicator dilution equations.<sup>17</sup> Second, Transonic cites the proof of its own expert Daniel Maynes for the proposition that the equations are equivalent.<sup>18</sup>

The problem with these authorities, though, is that even if Transonic is correct that they demonstrate to a mathematical certainty that the NMT and the Transonic equations ultimately end up producing similar results, they require much more than merely "altering" a few terms in the Transonic equation to get to the NMT equation. These significant transformations exceed what *Transonic II* contemplated was covered by the patent. Moreover, if NMT technology works, this equivalence is precisely what we would expect to see. In other words, if both equations solve for  $Q$ , it follows logically that the equations could be put on opposite sides of an equal sign, i.e., if  $NMT\ Equation = Q$  and  $Q = V/S$ , it follows that  $NMT\ Equation = V/S$ . Such a proof does not establish that the two equations share any core mathematical relationship. It just proves, as Dr. Leypoldt was trying to show Dr. Krivitski heuristically,<sup>19</sup> that the  $\Delta H$  method

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<sup>17</sup>Decl. of Michael K. Friedland in Supp. of Transonic's Opp. to NMT's Mot. for Partial Summ. J. of Non-Infringement, Ex. 9, Letter from Dr. Leypoldt to Dr. Krivitski of Mar. 19, 1997, at 1.

<sup>18</sup>*Id.*, Ex. 12, Expert Witness Report of Dr. Daniel Maynes at 6-14.

<sup>19</sup>Decl. of Timothy B. Smith in Supp. of NMT's Mot. for Partial Summ. J. of Non-Infringement, Ex. 2, Depo. of John Kenneth Leypoldt at 223-26.

works.

Accordingly, the court concludes that the proofs do not demonstrate that the respective equations embody the same mathematical relationship. To the contrary, they show that the equations are distinct in more ways than just altered elements. Thus, the court need not review the evidence as to the reliability of these proofs, and summary judgment is proper in favor of NMT.

### C. *Doctrine of Equivalents*

The foregoing analysis establishes that  $\Delta H$  does not literally infringe on the '989 patent. However, as directed by the Federal Circuit in *Transonic II*, this court must consider whether the patent infringes under the doctrine of equivalents. The court concludes it does not.

To establish that  $\Delta H$  infringes under the doctrine of equivalents, Transonic must show that "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention."<sup>20</sup> However, "[w]here an accused device performs substantially the same function to achieve substantially the same result but in a substantially different manner, there is no infringement under the doctrine of equivalents."<sup>21</sup> Moreover, the doctrine of equivalents is also subject to prosecution history estoppel, which "requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process" and "ensures that claims are interpreted by reference to those 'that have been cancelled or rejected.'"<sup>22</sup> Although the Supreme Court in *Festo v. Shoketsu Kinzoku Kogyo Kabushiki*

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<sup>20</sup>*Warner-Kenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997).

<sup>21</sup>*Dolly, Inc. v. Spalding & Evenflo Cos., Inc.*, 16 F.3d 394, 400 (Fed. Cir. 1994).

<sup>22</sup>*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733 (2002).

rejected the Federal Circuit's holding that estoppel was a complete bar to the doctrine of equivalents where a claim had been amended in prosecution, it noted that it has consistently applied prosecution estoppel where claims were amended "to avoid the prior art" and concluded that "[e]stoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope."<sup>23</sup> A reviewing court must "examin[e] the subject matter surrendered by the narrowing amendment,"<sup>24</sup> and "the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question."<sup>25</sup>

Here, it seems clear that difference between  $\Delta H$  and the '989 patent is substantial and that, given the nature of the amendment, Transonic is estopped from raising the doctrine of equivalents on this claim. Both *Transonic I* and *Transonic II* prominently cite from the patent prosecution, which narrowed the meaning of "calculating." As noted above, "Transonic distinguished a prior art reference during prosecution by explaining that 'in the present invention[,] shunt flow is calculated from a dialysis flow and a concentration curve measurement.'"<sup>26</sup> The Circuit went on to affirm that Transonic had "disclaimed any interpretations of the terms 'calculating' and 'determining' that do not reflect the stated significance of the disclosed equations,"<sup>27</sup> which this court understands to exclude equations that do not involve a dilution curve.

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<sup>23</sup>*Id.* at 735–736.

<sup>24</sup>*Id.* at 737.

<sup>25</sup>*Id.* at 740.

<sup>26</sup>75 Fed. Appx. at 775.

<sup>27</sup>*Id.* at 775–76.

Clearly, the amendment was made to distinguish the “calculating” under the ‘989 patent from prior art. At a minimum, the effect of this distinction was to show that technology that “calculated” blood flow without using a dilution curve was substantially different. More pertinent, however, the amendment narrowed the scope of the claim such that prosecution history estoppel applies. Transonic has not shown that this amendment did not surrender the equivalent in question here. Accordingly, summary judgment is proper in favor of NMT that  $\Delta H$  does not infringe on the ‘989 patent under the doctrine of equivalents.

*D. Effect on Other Claims*

The foregoing analysis applies to the “calculating” and “determining” limitations of claims 1 and 9 of the ‘989 patent. *Transonic II* made clear that the means-plus-function limitations of claims 24 and 32 turned on this same issue: “The functions both require ‘calculating.’ Accordingly, they are also limited by the specification and the prosecution history to the use of the mathematical principles disclosed in the ‘989 patent.’”<sup>28</sup> Thus, having held that the NMT technology does not use the mathematical principles disclosed in the Transonic patent, the court cannot see how Transonic would be able to establish an infringement of these claims and concludes that summary judgment in NMT’s favor is proper on claims 24 and 32 as well. Because the other claims at issue are dependent on claims 1 and 9, summary judgment is also proper on them. This reasoning also shows that the preliminary injunction was improper, and the prior grant of NMT’s motion for an opportunity to prove damages is reinstated.

## V. SALINE DILUTION METHOD

The foregoing analysis pertains primarily to the  $\Delta H$  technology and provides little insight

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<sup>28</sup>*Id.* at 778.

on whether the Saline Dilution method infringed the '989 patent. NMT does not contest Transonic's argument that its Saline Dilution method infringes on the '989 patent. Instead it claims that Transonic is not entitled to recovery because it has not established that the Saline Dilution method was ever used after the '989 patent issued. The record reflects that NMT stopped promoting the Saline Dilution method once the '989 patent was issued.<sup>29</sup> Transonic's only evidence to the contrary is a series of studies a Masters Thesis written by Deniz Yazar, which may have involved the Saline Dilution method. However, the undisputed evidence shows that any such studies were completed prior to October 14, 1997,<sup>30</sup> which is before the '989 patent issued. Accordingly, summary judgment is proper in NMT's favor on the Saline Dilution method.

## VI. GO-NO GO METHOD

The central issue on this method, as with  $\Delta H$ , is whether the operative equation embodies the same relationship as in the '989 patent. NMT argues that the Go-No Go method calculates reverse line recirculation rather than access blood flow. Transonic concedes that it cannot challenge the equations involved in calculating reverse line recirculation but argues that the infringing equation is the one that relates reversed-line recirculation to access blood flow. Indeed, Maynes' proof that the Go-No Go equation is algebraically equivalent to Equation 5 of the '989 patent rests on the assumption that the Go-No Go method uses the equation  $Q_a = Q_b [(1 /$

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<sup>29</sup>Decl. of Jonathan H. Takei in Supp. of Def. NMT's Mot. for Summ. J. of Noninfringement, Ex. 7, Depo. of David Robert Bell at 304:14-306:3.

<sup>30</sup>Decl. of Dr. John (Ken) Leypoldt (Aug. 16, 2001) 1, ¶ 5.

$R_{rev}) - 1]$ .<sup>31</sup> Even if Maynes' analysis is correct, NMT rightly points out that Transonic has not established the use of this equation in the Go-No Go method. Accordingly, summary judgment for NMT is proper on this method as well.

## VII. CONCLUSION


Based on the foregoing, the court grants NMT's Motion for Summary Judgment. The court concludes that the  $\Delta H$  method does not infringe on the '989 patent because it does not "calculate" blood flow through the shunt as that term is used in the patent. The Saline Dilution method also does not infringe because it was never used after the '989 patent was issued. And the Go-No Go method does not infringe because it does not use any equations from the '989 patent.

The court also reinstates its prior grant of NMT's motion to prove-up damages. NMT is directed to file a new, updated memorandum supporting its damages by August 27, 2004. A new, updated opposition is due September 10, 2004. The court anticipates resolving this issue on the pleadings. Accordingly, both sides should include any appropriate supporting affidavits.

SO ORDERED.

DATED this 6th day of August, 2004.

BY THE COURT:



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Paul G. Cassell  
United States District Judge

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<sup>31</sup>Decl. of Benjamin A. Katzenellenbogen in Supp. of Transonic's *Revised* Mot. for Partial Summ. J. of Patent Infringement, Ex. 6, Decl. of Daniel Maynes at ¶¶ 12, 17.

tsh

United States District Court  
for the  
District of Utah  
August 10, 2004

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